K121043

FEB 22 2013

Name of Device	Spectral OCT/SLO Microperimeter Device
Common or Usual Name	Optical coherence tomography and microperimeter (21 C.F.R. § 886.1570 & § 886.1605)
Classification Name	Optical coherence tomography and microperimeter (21 C.F.R. § 886.1570 & § 886.1605)
Product Code	OBO & HPT
Submitter	Optos plc, Queensferry House, Carnegie Business Campus Dunfermline, Fife, KY11 8GR United Kingdom Phone: 011 44 1383 843300 Facsimile: 011 44 1383 843333
Contact Person:	Robert Tweedlie Ph.D.
Date Prepared	14 February 2013
Predicate Device	Nidek MP-1 Microperimeter

Indications for Use

The Optos spectral OCT/SLO with Microperimetry is indicated for use for in vivo viewing, axial cross section, and three dimensional imaging and measurement of posterior ocular structures including retina, macula, retinal nerve fiber layer and optic disk. It is used as a diagnostic device to aid in the detection and management of ocular diseases affecting the posterior of the eye. In addition, cornea sclera and conjunctiva can be imaged with the system by changing the focal position.

The additional microperimetry functionality is indicated for use as a fixation examiner locating the patient's fixation site and, by using the patient's subjective answer to light stimuli, generating a sensitivity map of the inspected retinal region.

Principles of Operation and Technological Characteristics

The Optos OCT/SLO Microperimeter is a non-contact, non-invasive, high-resolution device that is an add-on module to the FDA-cleared Optos Optical Coherence Tomography/Scanning Laser Ophthalmoscope (OCT/SLO). The OCT/SLO is a computerized instrument that employs non-invasive, low-coherence interferometry to acquire simultaneous high-resolution cross-sectional OCT and confocal images of ocular structure, including retina, retinal nerve fiber layer, macula and optic disc of the eye. The light source used for this is a super luminescent diode (SLD).

The microperimetry test runs simultaneously with the confocal ophthalmoscope (SLO) and provides real-time tracking of retinal motion and patient fixation during the exam. Additionally, the patient's subjective response by depressing a button to light stimuli generates a sensitivity map for the inspected retinal region. The variable light stimuli are generated by an organic light emitting diode (OLED).

Clinical Evaluation

a) Precision Study

A precision study was conducted that used 3 devices (each with a different operator). Each device was used to measure 4 normal subjects and 4 subjects with relevant eye pathology, with a total of 12 subject eyes measured across all three devices. The eye pathologies used for the study are early and intermediate Age-Related Macular Degeneration, Geographic Atrophy, Diabetic Retinopathy (mild, moderate, severe), Macular Edema secondary to Diabetes, Retinal Vein Occlusion, Central Serous Retinopathy, Pattern Dystrophy, Epiretinal Membrane or Macular Hole. For each subject, one eye was evaluated using 3 replicates with repositioning at the start of each test.

A nested study design was used and the results achieved were as follows:-

#Patient	12 Normal	12 with pathology
Overall Mean	16.16 dB	12.23 dB
Overall Standard Deviation	1.735 dB	3.508 dB
Repeatability SD	0.531 dB	0.682 dB
Repeatability SD Limit*	1.49 dB	1.91 dB

*The repeatability limit is the upper 95% limit for the difference between repeated results. The Repeatability Limit is defined in ISO 5725-1 and ISO 5725-6 and equates to 2.8 times the repeatability standard deviation. It should be noted that the minimum to maximum repeatability for normal and eyes with pathology can vary by a factor of approximately 10. The table provides an estimate of the average repeatability, as determined during the clinical evaluation of the device. Users should note that repeatability varies between patients.

b) Agreement study

An in house study was conducted on 20 normal eyes and 20 diseased eyes using the Optos and the predicate device.

Excluding the extremes of the attenuation scale, the agreement between the devices approximates to ± 1 attenuation steps. At the attenuation scale extremes the agreement is ±2 steps as a worst case.

Due to background illumination differences between the Optos and predicate device, there is a systematic difference of 1 ½ steps (3dB's) in the means for normal eyes. The mean difference between devices for diseased eyes is a ¼ step (0.5dB's). The mean difference between devices for diseased eyes is smaller than the mean difference between devices for normal eyes because, at higher levels of illuminance, the background level appears to have less of an effect on diseased eyes. This systematic bias between the Optos device and the predicate device was not consistent across all measurement values. For the normal eye, the average attenuation is from 17.2 to 19.0 dB. In this range, the difference between the predicate and the Optos device decreases from approximately 5.3 to 2.0 dB. For the diseased eyes, the difference (Predicate - Optos) increases from -4.0 dB to 2.0 dB when the average measurement ranges between 5.0 and 19.0 dB. This pattern was observed because the predicate reading is higher at high mean attenuation values (approaching 20 dB's) and lower at low mean attenuation values when compared to the Optos OCT/SLO device. The differences in agreement between the Optos device and the predicate necessitate that measurements obtained from these two devices are not interchangeable.

Substantial Equivalence

In terms of microperimetry, the Optos OCT/SLO has the same intended use and indications for use and similar principles of operation and technological characteristics as the predicate device. The Optos and

the predicate device both require a patient response via a button push to light stimuli of varying intensity. The control, pattern and duration of these stimuli are very similar. The minor technological differences mainly relating to the use of a light emitting OLED in the Optos device and a backlit liquid crystal display (LCD) do not raise any new questions of safety and effectiveness. Thus, the Optos OCT/SLO Microperimeter is substantially equivalent to the legally marketed Nidek MP-1 Microperimeter (K023719)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 22, 2013

Optos PLC
% Mr. Edward C. Wilson, Jr.
Hogan Lovells, US LPP
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004

Re: K121043
Optos Spectral OCT/SLO Microperimeter (MP)
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: HPT and OBO
Dated: January 30, 2013
Received: January 30, 2013

Dear Mr. Wilson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Deborah L. Falls

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose, and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Statement for Indications for Use

510(k) Number (if known): K121043

Device Name: Optos Spectral OCT/SLO Perimeter

Indications For Use:

The Optos spectral OCT?SLO Micorperimeter is indicated for use for in vivo viewing, axial cross section, and three dimensional imaging and measurement of posterior ocular structures including retina, macula, retinal nerve fibre layer and optic disk. It is used as a diagnostic device to aid in the detection and management of ocular diseases affecting the posterior of the eye. In addition, cornea scleraa dn conjunctiva can be imaged with the system by changing the focal position.

The micorperimetry functionality is indicated for use as a fixation examiner locating the patient's subjective answer to light stimuli, generating a sensitivity map of the inspected retinal region.

Prescription Use _X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Marsha L. Burke Nicholas
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(Division Sign-Off)
Division of Ophthalmic and Ear, Nose
And Throat Devices
510(k) Number K121043